



# Photobiomodulation

The Next Era of Medicine



National Foundation for  
**Integrative Medicine**

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CHANGING HEALTHCARE WITH 21ST CENTURY SOLUTIONS



## Project One

# PHOTOBIO-MODULATION

**Objective:** Gather comparative evidence and publish which LASER frequencies and power settings are optimum to safely, efficiently and affordably reduce pain and inflammation.

**Background:** LASERs have been known to effectively reduce inflammation and pain for decades. The acknowledged mechanism of action is the photon displacement of nitric oxide from cytochrome oxidase within the ATP (Adenosine Triphosphate) energy cycle. This allows increased power at the cellular level. Many believe that if a cell has adequate energy, it stays healthy. LASERs represent a wonderful non-opiate alternative for treating and controlling pain already widely used in many other countries. LASERs have been FDA cleared in this country for decades.

**Problem:** Despite volumes of peer reviewed published literature, western medicine remains unconvinced and slow to adopt. One problem is the LASER industry's inability to determine or agree which frequencies and power levels are the most effective. This leads to many claims and leaves providers unsure of how to proceed. Western clinicians incorrectly conclude the modalities are nascent, when in fact, there is more evidence available supporting pain control with LASERs than there is supporting the current modalities of treatment.

**Project:** NFIM will launch a 2-year translational effort to determine which claims and which frequencies are clinically relevant in the primary care setting. The research team will focus on determining what if any benefit is achieved with increasing powers into Class IV levels. This will be done through side-by-side comparisons of various popular devices available to clinicians. Additionally, the team will focus on the various frequency claims to either validate the specificity allegedly required, or prove that a broader set of frequencies are clinically useful and can be adopted. Ultimately this informs clinicians on which LASERs to use.

**Budget:** The required \$4M budget for 'Project One' includes obtaining the devices and creating the independent research partners around the country. NFIM will provide training, equipment, admin support, data analysis and the informatics platform to capture the data turning it into medical 'evidence' that will stand up to western medical scrutiny. This will inform the next generation of pain control modalities and standards of care.

**Principles:** At no time will NFIM accept any donations from LASER manufacturers while this study is ongoing or in its publication cycle. Please refer to NFIM's R&D principles covered elsewhere in this brochure that preclude any conflicted influence on NFIM's research products. Above all else, NFIM values full disclosure and transparency affording researchers an ability to assess the data and come to their own conclusions. We will never knowingly violate this trust.

## The Advent of Laser Therapy

Lasers have an extensive history of positive therapeutic effects for pain and wound healing. This is supported by gigabytes of published peer reviewed literature. The technology continues to push the envelope further increasing possibilities for patient benefits. The FDA has cleared or approved light for pain and wound healing treatments for decades now. It is proven safe and effective with few side effects ever reported. The industry is exploding with light devices boasting various powers and frequencies, all claiming that they are the 'best' for therapeutic interventions. Clinicians and patients have no idea of whose claims are correct and true for which clinical applications. Devices now range in power from simple colored light, to the high end products sporting over 70W of healing energy. Frequencies range from below visible light up through the visible spectrum and beyond with each manufacturer describing in their marketing brochures why their frequency and power selections, and absorption profiles are ideal. Lots of scientific gaps exist that precludes physicians and patients from making informed device and treatment decisions. These are fundamental questions that the industry never has been able to adequately address. These devices have never been directly compared to each other in practical clinical settings nor to the other typical non-energy modalities for pain control or wound healing to determine which methods and which energy parameters are the most important for great patient outcomes.



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## An Unbiased Assessment

The Photobiomodulation and LASER clinical community consisting of designers, manufacturers and clinicians seem committed to supporting ongoing scientific discovery to fully understand how light frequencies help control pain and possibly ameliorate other human pathological conditions. Yet, it also seems willing to allow a degree of chaos by not addressing key knowledge gaps, which have existed in the industry for decades. Research dollars remain scarce and there are relatively few clinical researchers in this area. There is professional disagreement on which frequencies and what power levels are best for clinical outcomes. NFIM will help make these answers clearer.

A few manufacturers have approached NFIM offering well-intentioned donations to partially offset and allow NFIM to more quickly conduct independent clinical studies in this research area. NFIM turned them all away despite their benevolent intentions insuring the Foundation can maintain its concrete separation between our research partners and conflicted funding sponsors. While this deliberate resistance to accepting money from industry stakeholders may impede rapid clinical studies and compel the Foundation to look harder for philanthropic donors, NFIM remains committed to this approach. This is the only way to remove any real or apparent of conflict of interest among its research projects. Though it will take longer to execute studies, once completed, everyone will know that the data is the whole data, and nothing but the truth.

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## An Unbiased Assessment

To that end, NFIM has not, nor will it accept donations from any LASER manufacturer until the Foundation has independently conducted several comparisons that add to the industry and clinical knowledge base. All results will be shared with patients, physicians, researchers and manufacturers to advance the entire community's knowledge base. The goal is to advance this scientific body of knowledge by assisting all stakeholders to better determine where the next scarce resource should be invested or deployed in patient care, research or device manufacturing.

NFIM will ensure the integrity in the scientific processes it participates in. The Foundation has no stake in any device or pharmaceutical company.

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## ABOUT NFIM

### Changing Healthcare with 21st Century Solutions.

The National Foundation for Integrative Medicine's ([www.NFIM.org](http://www.NFIM.org)) mission is to explore, analyze and when appropriate transition novel technologies that are efficacious, safe and affordable. The NFIM leadership team consists of distinguished un-retired professionals ranging from the Chairman of the Joint Chiefs of Staff, several Surgeons General, Assistant Surgeons General, general officers, esteemed clinicians, researchers, veterans, civic leaders and people just like you who are committed to identifying and validating new alternatives for our failing medical systems. NFIM's tenets are transparency and integrity with many checks and balances. We are open to everything, yet vested in nothing. We believe in God, but everyone else must bring data! NFIM partners with many agencies and entities providing leadership and its non-conflicted culture and perspectives to make meaningful progress.

NFIM is a clinical host, facilitator and participant when invited into studies or forums that advance medical science or policy. NFIM continually self-checks itself to remain free of conflict of interest (COI) or 'greedy' behavior.

More than anything else, NFIM guards and honors its covenants with the clinicians and patients who rely on NFIM's work for their source of trusted data, information and knowledge. We will never knowingly violate that trust.

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## It's the DATA that Matters.

It is increasingly difficult today to create medical truth. Part of the dilemma stems from the fact that many studies are embargoed from publishing if results do not support the sponsor's financial interests. Principle Investigators (PI's) are frequently required to sign gag clauses as a condition for receiving research money. These gag clauses restrict the researcher from disclosing results if the data are not pleasing to their paying sponsors. Not publishing and not sharing all data from studies leads the professional community to an inaccurate picture of the truth on any particular topic. This has happened. Clinicians and patients were led astray to the point where patients were harmed. We now live in a world where even experts cannot reliably find truthful science, or spot and challenge questionable conclusions. Yes, though scandalous, it remains the truth. Those in charge prefer the status quo. Panels of experts have repeatedly recommended the detailed changes needed to return academic integrity into medical research, but those changes have not been adopted or enforced by those with scientific oversight and review.

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## It's the DATA that Matters.

This should not be acceptable to patients nor their physicians – and it's not acceptable to NFIM. Yet this lack of accountability currently exists under the darkness of professional ignorance. NFIM pledges that all studies it begins will be accounted for and available for public review. All protocols will be submitted to Institutional Reviews Boards (IRB) with specific paragraphs indicating that all data (once personal information is adequately redacted) will be available for other researchers to review as well. The intent is to return transparency into clinical research that has been deliberately contracted out by those funding sponsors who believe they can buy favorable 'fake' science.

NFIM pledges to start reversing these destructive research practices that ruined the world's best clinical research enterprise. NFIM will model and show that sharing data and focusing on advancing science can still work as it did in America over the past many decades.



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## Maintaining Scientific Integrity and Independence

The Foundation believes by teaming with public agencies that are NOT dependent on research funds from stakeholder and conflicted funding sources, that we can reverse the sinister bias that has effusively infiltrated the US medical research enterprise. NFIM is creating strategic partnerships with the Department of Defense, Department of Veterans' Affairs, academic centers and various medical centers and clinics around the country. These partnerships are based on the open sharing of raw study data and full protocols, elimination of gag rules on investigators and the mutual desire to publish all research results transparently regardless of where the data and results lead. Truth on every level will return to medical research when these tenets are followed and rigorously enforced. NFIM is committed to doing our share.

A new dawn is rising. It promises the overdue return to an old paradigm of research integrity that made this country's medical research the best in the world. We want to recapture America's former reputation and this is the first step in getting there.

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## Informatics Platform

The NFIM informatics / data platform is a government certified meaningful use (MU) CCHIT certified medical record system that has been successfully deployed to numerous free clinics in West Virginia and Virginia over the past several years. Its highly secure platform is HIPAA compliant offering auditable and role-based access minimizing unauthorized disclosure of any encrypted information or data. It is one of NFIM's key assets for gathering, storing and analyzing clinical research data and turning it into usable medical information. NFIM has secured licenses for this very hearty platform for the next 99 years insuring our clinical partners will never be left with unsupported informatics. NFIM has secured a license that permits required changes to the source code if ever required for research or any exigency at NFIM's discretion. This flexible platform has proven to be robust and will be deployed in a sophisticated network among NFIM collaborators around America and the world to share and push medical research data.

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## Informatics Platform

This capability is one key to NFIM's commitment to rapidly collecting research data, and processing it into medical evidence to overcome the medical profession's dismal 17-year transition cycle of new technologies. This platform will scale and allow much larger data aggregation than is done today.

This long transition cycle can and must be shortened for the benefit of America's imploding health care system. The current antiquated and conflicted system controls transition timelines employing barriers based on different levels of required medical evidence. NFIM is securing the next generation of strategic partners to directly share study results and practical clinical evidence with tens of thousands of providers and hundreds of thousands of patients to create a new culture that can safely embrace new technology faster.

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## The Future is Laser Bright

Energy medicine represents a wonderful addition to the arsenal that physicians and their patients can safely employ for a myriad of conditions. While current FDA approval is for pain and wounds, NFIM is eager to scientifically start the necessary work to show other wonderful unintended consequences that add to the vibrant health of patients who are treated with light energy. While the expectations are extraordinary based on decades of observed clinical outcomes and case studies from around the world, more work is required to fill-in the remaining clinical gaps. NFIM is committed to sharing all the data, regardless of where it leads.

Energy is natural. Everything is dose dependent. Too much of anything kills. A correct level of energy is required in every cell for optimal health. New western understanding of mitochondrial health is suggesting what the rest of the world has known for centuries. Optimal cell health leads to the optimal health of the entire body. Eastern medicine has acknowledged this concept of optimum cell energy for thousands of years and Europeans are decades ahead of us. If we are to rapidly catch up to the rest of the world, we must demonstrate that the world's energy devices work here in America too. Of course they do, as we have been observing this for decades, but few physicians have been taught any of this in medical school. How can that be? The American health care system demands clinical trials for acceptance. This same evidence will be required for health care insurers and payors to cover the expenses and compensate providers who offer better outcomes with these superior technologies.

“Healing is a matter of **time**, but it is sometimes also a matter of **opportunity**.”

*Hippocrates*

## Join NFIM in Our Mission

These technologies are efficacious, safer and more affordable, but that claim and expectation still needs to be demonstrated in pragmatic clinical trials and compared to current standards of care.

Come join our team! Consider contributing to this vision of unbiased medical research so you and your physicians can make better decisions for your family's health. It will be too late if you wait until your family actually needs these answers.

***If you don't contribute to your health, then who will?***

***If not now, then when?***

**Don't delay, please donate money or your time, and donate today!**

Visit [NFIM.org](http://NFIM.org) for details.

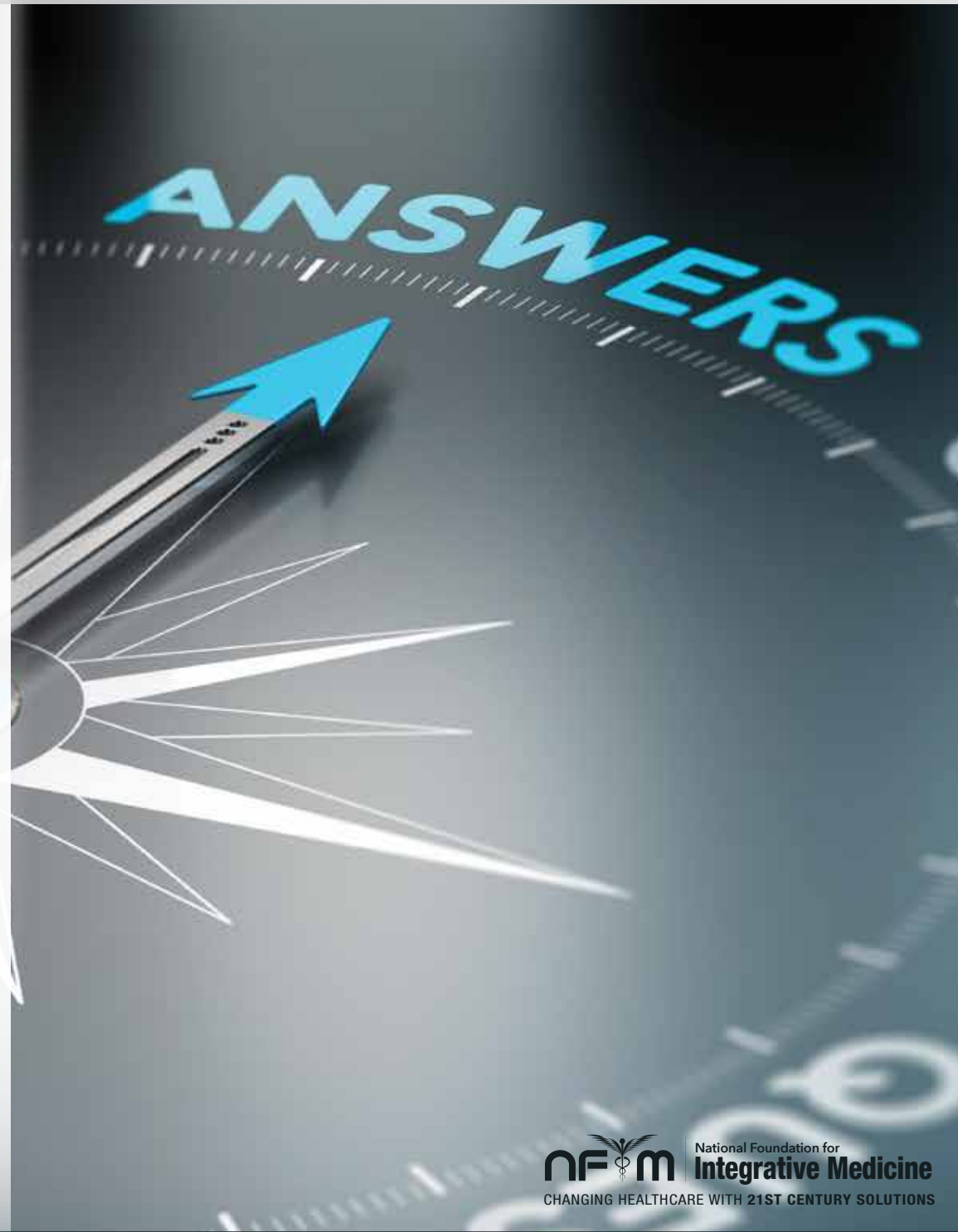


## Our Cultural Values

NFIM is an organization focused on outcomes. We are on a mission to answer the nation's demand for a more effective, safer and affordable health care system. Our clinician partners have demonstrated this can be done at the clinic and hospital level and now we will work to demonstrate it can be scaled beyond to address entire regions and specific health issues like opiate addiction and posttraumatic stress disorders. Our observational data says this can work, and the nation needs it to work as well.

The distribution of donated funds reflects our commitment and altruistic cultural values. Our officers and advisors currently take neither salary nor stipends, as that would diminish program monies too much at this nascent point in the Foundation's journey. We expect this to change soon, and are committed to remaining below the non-profit standard thresholds for salaries and overhead expenses. We value good personnel and acknowledge the need to pay competitive salaries to attain the best and brightest which are necessary to conceive new ideas that America desperately needs. For now, we depend and enjoy only on contributions from dozens of philanthropic contributors, from all walks of life to sustain this noble vision and journey.

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## Distribution of Donated Funds

Do you believe that what we are doing is critically important for you and your family? Please consider joining or donating to our team.

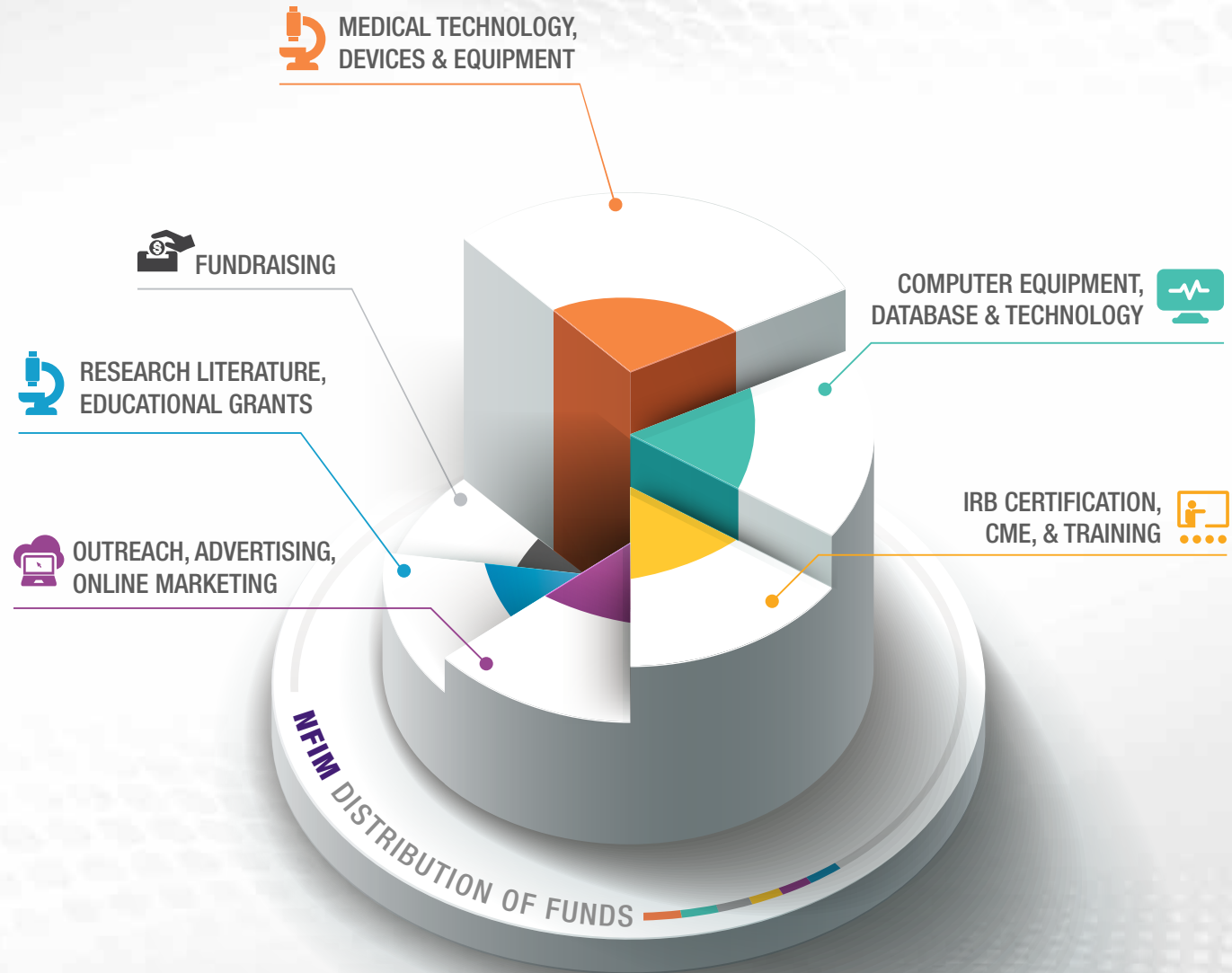
The breakout of funds demonstrates our commitment to mission.

Become part of something bigger than self ..... Something that the country needs so desperately right now ... and Something your family will need soon whether for your parents, your children or a friend!

Everyone can contribute in their area of expertise. Come reach out to us and answer the grass roots call to improve America's health system to make it safer and more affordable. We have lost the understanding of what it means to all be in a life and death struggle together.

**Join us and donate today!**

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**If not you - than whom?**

**If not now - then when?**

**NFIM: A 501(c)3 Charitable Organization**

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